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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/599,753 | 07/25/2007 | Henrik Arnberg | 15665-010US1 | 3748 |
| 26191 7590 05/26/2010 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | EXAMINER CHANDRA, GYAN | |
| | | | ART UNIT 1646 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/599,753 | Applicant(s) ARNBERG, HENRIK | |
| | Examiner GYAN CHANDRA | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 18, 21-26 and 32-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 18, 21-26 and 32-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 3/24/2010 is acknowledged and fully considered.

Status of Application, Amendments, And/Or Claims

The amendments to claims 16, 35 and 36 have been made of record.

Claims 16, 18 and 21-26 and 32-48 are pending and under examination.

Response to Arguments

Claim Objections-withdrawn

The objection of claim 16 for missing the article "a" before the term "periodontal disease" is withdrawn in view of applicants' amendments to the claim.

Claim Rejections - 35 USC § 112, second paragraph-withdrawn

The rejection of claims 35 and 36 because the claims are incomplete for missing a period at the end the claims is withdrawn in view of Applicants' amendment to claims 35 and 36.

Claim Rejections - 35 USC § 102-withdrawn

The rejection of claims 16, 22-26, 36-42, and 48 under 35 U.S.C. 102(b) as being anticipated by Awaya et al (US patent No. 5,976,523) is withdrawn in view of Applicants' arguments which have been found persuasive.

Claim Rejections - 35 USC § 102-maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1646

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

It is noted to applicant that claims 38 and 39 were inadvertently were left out from the instant rejection but the claim limitations were included in the rejection (see page 5 of the office action of 12/28/09).

Claims 16, 18, 22-26, 36-42, and 48 remain rejected under 35 U.S.C. 102(e) as being anticipated by Erickson-Miller et al (US pub. No. 20070105824) for the reasons of record on pg. 5-6 of the office action of 12/28/09 and as discussed below.

The instant claims are broadly drawn to a method of treating a mammal suffering from a periodontal disease or inducing tooth calcification comprising locally administering by injection in the proximity of the periodontal disease a therapeutically effective amount of a composition comprising at least one granulocyte-macrophage-colony stimulating factor (GM-CSF) polypeptide (claim 16), wherein the periodontal disease is gingivitis or periodontitis (claims 18, 37), wherein the composition the composition comprises 5-800 ug of GM-CSF per unit dosage (claims 22-23, 38-39), wherein the composition is administered at intervals ranging from once a day to once every third week (claims 24, 40), wherein the composition is administered a total of 1 to 3 times for a period of one week (claims 25, 41), wherein the composition comprises a

Art Unit: 1646

therapeutically effective amount of at least one other active ingredient (claims 26, 42), wherein the mammal is a human (claims 36, 48).

Applicants argue (see page 9 of Response) that GM-CSF is disclosed to use in combination with TPO for treating a degenerative disease including periodontal disease. They argue that the invention of Erickson-Miller et al is broadly drawn to molecules which have anti-apoptotic, survival or proliferative properties for stem cells or other cells expressing TPO receptors. They argue that Erickson-Miller et al fail to disclose GM-CSF for treating bacterial component of periodontal disease or a bacterial infection. They argue that a word search in the prior art does not show the term “bacteria” or “bacterial”.

Applicants’ arguments have been fully considered but they are not persuasive because the instant claims are not drawn to a composition “consisting of GM-CSF” rather the claims are drawn to a composition “comprising GM-CSF” and therefore, the composition can have a TPO agonist. Because Erickson-Miller et al teach treating a degenerative disease including a periodontal disease such as gingivitis, which can be due to a bacterial infection (see claim 5), the prior art implicitly anticipates the instant invention.

The specification on page 1, discloses that periodontal diseases are caused by bacteria and toxins in dental plaque, which is a sticky colourless film constantly forming on the surfaces of the teeth. There are many forms of periodontal disease. The most common ones include gingivitis, aggressive periodontitis and chronic periodontitis. Gingivitis is the mildest form of periodontal disease, causing the gingiva to become red, swollen, and bleed easily. Gingivitis, if untreated, is thought to develop into periodontitis.

Art Unit: 1646

In periodontitis the infection has progressed to involve the oral tissues which retain the teeth in the jawbone. If untreated, periodontitis ultimately leads to loss of the affected tooth. It is also noted to applicants that claim 16 only requires treating any periodontal disease and claim 17 says that the periodontal disease is gingivitis but the claim not even require that gingivitis is due to bacterial infection. Additionally, the teachings of Erickson-Miller for treating gingivitis by a composition comprising GM-CSF would still anticipate the instant invention. Applicants' arguments that the reference Erickson-Miller et al does not recite the term "bacteria or bacterial" and only teaches administering GM-CSF to treat a periodontal disease because of its anti-apoptotic activity have been fully considered but they are not persuasive because Erickson-Miller et al teach administering a composition comprising GM-CSF to treat a periodontal disease (see claim 16). Additionally, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1646

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 32-35 and 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson-Miller et al (US pub. No. 20070105824) in view of O'Uchi et al (US Patent No. 6,682,718) for the reasons of record on pg. 6-9 of the office action of 12/28/09 and as discussed below.

Applicants argue (pages 12-14) that Erickson-Miller et al teach to use GM-CSF with a TPO agonist because of its "anti-apoptotic, survival, or proliferative properties" on cells. They argue that Erickson-Miller et al neither teach nor suggest that TPO in combination to GM-CSF has anti-bacterial activity to treat a periodontal disease. Applicants argue that they have discovered an unknown and unexpected property of GM-CSF. Applicants argue that in contrast to all the references the specification has actually reduced to practice the claimed method in a clinical setting.

Applicants' arguments have been fully considered but they are not persuasive because Erickson-Miller et al teach administering a composition comprising GM-CSF with a TPO agonist for treating a periodontal disease (see claim 5). Applicants' arguments that the reference does not disclose that a periodontal disease is because of bacterial infection

Art Unit: 1646

have been fully considered and they are persuasive but it is well known in the art that a periodontal disease such as gingivitis is caused by a bacterial infection. The specification on page 1, discloses that periodontal diseases are caused by bacteria and toxins in dental plaque, which is a sticky colourless film constantly forming on the surfaces of the teeth. There are many forms of periodontal disease. The most common ones include gingivitis, aggressive periodontitis and chronic periodontitis.

Gingivitis is the mildest form of periodontal disease, causing the gingiva to become red, swollen, and bleed easily. Gingivitis, if untreated, is thought to develop into periodontitis. In periodontitis the infection has progressed to involve the oral tissues which retain the teeth in the jawbone. If untreated, periodontitis ultimately leads to loss of the affected tooth. It is also noted to applicants that claim 16 only requires treating any periodontal disease and claim 17 says that the periodontal disease is gingivitis but the claim not even require that gingivitis is due to bacterial infection. Additionally, the teachings of Erickson-Miller for treating gingivitis by a composition comprising GM-CSF would still render the instant invention obvious. Additionally, regarding applicants' arguments that they have discovered an unknown and unexpected property of GM-CSF, it is noted that been fully considered but they are not persuasive Erickson-Miller et al teach administering a composition comprising GM-CSF with an agonist of TPO to treat a periodontal disease (see claim 16). It is noted to applicants that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347,

Art Unit: 1646

51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). It is noted to applicant that amendments to claim to something like " a method of treating a mammal suffering from a periodontal disease comprising locally administering.....a therapeutically effective amount of a composition **consisting of GM-CSF**" would be considered favorably.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
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/Robert Landsman/
Primary Examiner, Art Unit 1647